Exhibit A

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION This Document Relates to All Cases Filed Against Defendant Personal Care Products Council	**Civil Action No. 3:16-md-2738-FLW-LHG** **MDL No. 2738**

THE PLAINTIFFS' STEERING COMMITTEE'S SURREPLY IN RESPONSE TO DEFENDANT PERSONAL CARE PRODUCT COUNCIL'S REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

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In Defendant Personal Care Products Council's Reply in Support of its Motion for Summary Judgment (ECF No. 13692, hereinafter "Reply"), PCPC raises new arguments and cites to authority not discussed in its initial Memorandum of Law in Support of its Motion for Summary Judgment (ECF No. 2738). PCPC also misstates points raised by Plaintiffs in their Opposition (ECF No. 13573, hereinafter "Opposition") that require clarification. Plaintiffs, having moved for leave to file a Surreply, hereby respond to these new arguments, new citations, and misstatements. The issues that Plaintiffs will address are the following:

1. PCPC's citations to new cases in support of its First Amendment and *Noerr-Pennington* arguments and misstatements about Plaintiffs' exhibits attached to Plaintiffs' Opposition;
2. PCPC's new and incorrect arguments relating to choice of law;
3. PCPC's new issues and arguments relating to its Anti-SLAPP defense; and
4. PCPC's misstatements of the evidence relating to Plaintiffs' arguments about the common law claims at issue.

ARGUMENT

I. THE FIRST AMENDMENT DOES NOT IMMUNIZE PCPC FROM LIABILITY

PCPC claims it is immunized from liability pursuant to the First Amendment of the United States Constitution and the *Noerr-Pennington* doctrine. However, what Plaintiffs seek to litigate does not present a First Amendment issue. PCPC has no First Amendment right to misrepresent and obscure information from the public about the safety of talcum powder, and merely having a government entity in the room does not amount to "petitioning" under *Noerr-Pennington*. PCPC does not enjoy blanket immunity for its tortious conduct, it can be held liable for its conduct as a matter of law, and Plaintiffs' allegations against PCPC present genuine disputes of material facts rendering summary judgment inappropriate.

A. The First Amendment and *Noerr-Pennington* do not Apply to PCPC's Conduct.

PCPC attempts to invoke the First Amendment as a talisman through which the "right to petition" bestows blanket protection for otherwise tortious conduct. PCPC manifestly misrepresents the scope of the law; as neither the First Amendment nor *Noerr-Pennington* bear any relevance to this dispute. The protections contemplated by *Noerr-Pennington* have their roots in antitrust and similar anticompetitive behaviors, holding federal antitrust laws inapplicable to parties who attempt to influence government action for anticompetitive ends. *A.D. Bedell Wholesale Co. v. Philip Morris Inc.*, 263 F.3d 239, 250 (3d Cir. 2001). Even where the doctrine has been expanded to certain common-law torts, its application remains limited to the filing of claims in court or before administrative agencies as part of the protected right to petition, protections that bear absolutely no relation to PCPC's conduct at issue here. *Whelan v. Abell*, 48 F.3d 1247, 1254 (D.C. Cir. 1995). *Noerr-Pennington* was not contemplated to shield a party that wrongfully manipulates science and medicine to the detriment of public safety. Nor has any Court in this jurisdiction ***ever*** expanded the doctrine to immunize a party from liability for making misrepresentations about the safety of a product. The authority PCPC cites in its Reply support of its argument is wholly inapposite.

PCPC cites *Hernandez v. Amcord, Inc.*, 215 Cal. App. 4th 659 (2013) for the proposition that *Noerr-Pennington* immunizes defendants from liability in personal injury claims. *Hernandez* did not immunize defendants from liability but, instead, only held that "reliance on the *Noerr–Pennington* doctrine to ***exclude evidence*** in this negligence/strict liability case ***is a misapplication of the doctrine***." 215 Cal App. 4th at 680 (emphasis added). PCPC's reliance on *Pfizer Inc. v. Giles (In re Asbestos Sch. Litig.)*, 46 F.3d 1284 (3d Cir. 1994) is just as misplaced, as the Third Circuit held that a defendant could be held liable if it could be shown that the petitioning of a trade association was specifically intended to further wrongful conduct, such as

continuing to sell a dangerous product without a warning. *Id*. at 1292. Plaintiffs allege PCPC engaged in that very sort of conduct.

PCPC's reliance on *Tuosto* and *Hamilton* for the proposition that *Noerr-Pennington* bars liability in a personal injury tort claim is likewise strained: *Tuosto*'s application of the doctrine was limited solely to Phillip Morris' testimony before congressional committees regarding the safety of cigarettes and did not immunize it from liability for other misrepresentations, while *Hamilton* concerned a gun manufacturer's lobbying efforts to defeat legislation that would impose more stringent regulations on gun sales and ownership. The underlying facts in these cases are completely distinct from PCPC's conduct here. Contrary to PCPC's argument, there is no support for the proposition that *Noerr-Pennington* completely bars liability in product liability cases.

Historically, courts have invoked *Noerr-Pennington* "only where the cause of action itself is based on the act of lobbying or filing a lawsuit." *Mason v. Texaco, Inc.*, 741 F. Supp. 1472, 1500 (D. Kan. 1990), aff'd and remanded, 948 F.2d 1546 (10th Cir. 1991). The doctrine has no place here. Plaintiffs are not trying to restrain PCPC's speech or conduct towards the government; rather, Plaintiffs offer evidence about PCPC's knowledge, state of mind, and intent regarding the safety of talcum powder products. *See In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prod. Liab. Litig.*, 181 F. Supp. 3d 278, 306 (E.D. Pa. 2016) (denying motion *in limine* based on *Noerr-Pennington* to exclude evidence showing defendant's "knowledge, state of mind, or intent.").

B. Plaintiffs' Allegations are not Based on Protected Activity Under *Noerr-Pennington* or the First Amendment.

Even if *Noerr-Pennington* did apply to products liability claims, the facts alleged by Plaintiffs in this case do not implicate the sort of speech afforded constitutional protection under

the doctrine. Under *Noerr-Pennington*, those who petition any department of the government for redress are generally immune from statutory liability for their petitioning conduct. *Empress LLC v. City & County of S.F.*, 419 F.3d 1052, 1056 (9th Cir.2005). Petitioning activity includes "petitions directed at any branch of government, including the executive, legislative, judicial and administrative agencies." *Manistee Town Ctr. v. City of Glendale*, 227 F.3d 1090, 1092 (9th Cir. 2000). PCPC attempts to misrepresent the nature of Plaintiffs' claims by selectively directing this Court's attention to only communications that involve the FDA. However, as documented in Plaintiffs' Opposition, the full body of evidence reveals a decades-long course of obfuscation and misrepresentations to consumers on the part of PCPC about the safety of talcum powder products—conduct completely unrelated to petitioning the FDA or other government bodies and amounting to a genuine issue of material fact. (*See, e.g.*, Opposition Exhibits 8, 9, 11, 12, 25, 30, 106, 107.)

Even the particular conduct that PCPC cherry picks does not amount to constitutionally protected communications or activities under *Noerr-Pennington*. While some of PCPC's conduct did involve the FDA, those communications do not represent efforts directed to influence government action or pass favorable laws for competitive purposes as contemplated by *Noerr-Pennington*. *See Brownsville Golden Age Nursing Home, Inc. v. Wells*, 839 F.2d 155, 160 (3d Cir. 1988) (holding that *Noerr-Pennington* provides "that liability cannot be imposed for damage caused by inducing legislative, administrative, or judicial action[.]"). Even if PCPC's conduct did amount to petitioning (which it does not), its attempt to invoke *Noerr–Pennington* protection fails because the doctrine does not protect deliberately false or misleading statements. *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1123 (D.C. Cir. 2009) (finding deliberate misrepresentations intended to deceive the American public about the health effects

and addictiveness of smoking cigarettes not afforded *Noerr-Pennington* protection); *Whelan*, 48 F.3d 1247, 1255 ("Misrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process."). Plaintiffs' allegations against PCPC concern the very sort of misrepresentations analyzed in *Philip Morris* and *Whelan*, and *Noerr-Pennington* does not protect PCPC from liability. Moreover, because neither the First Amendment nor *Noerr-Pennington* is applicable to this dispute, PCPC's arguments regarding the "sham" or "fraud" exceptions to the doctrine are not relevant.

Finally, just because governmental agencies were privy to certain communications, PCPC is not automatically immunized from liability. For example, PCPC singles out citizens' petitions directed to the FDA regarding safety concerns about talcum powder as the type of communications that are immunized by the doctrine. However, in the context of similar product liability actions, courts have repeatedly held that such petitions do ***not*** enjoy *Noerr-Pennington* protections. *Wolfe v. McNeil-PPC, Inc.*, No. CIV.A. 07-348, 2012 WL 38694, at *6 (E.D. Pa. Jan. 9, 2012) (denying motion to exclude evidence related to citizen's petition submitted to FDA and noting that "the doctrine applies classically in the antitrust context"); *In re Tylenol*, 181 F. Supp. 3d 278, 304-06 (holding that the *Noerr-Pennington* doctrine "has no place" in a case in which "the plaintiff seeks to offer evidence about how the defendants attempted to influence, petition, or communicate with Congress and/or the FDA to show their knowledge, state of mind, or intent[,] and [i]t would be a stretch to say that Noerr-Pennington bars any use of any evidence of the defendants' petitioning of the government, and its agencies, or evidence of any communications with the FDA.).

PCPC "bears the ultimate burden of establishing the absence of disputed material facts that bear on the applicability of *Noerr-Pennington* immunity." *In re Elysium Health-Chromadex*

Litig., 354 F. Supp. 3d 330, 335 (S.D.N.Y. 2019). Because PCPC fails to demonstrate that its conduct amounts to protected speech, let alone that the First Amendment or *Noerr-Pennington* even apply in this case, its Motion for Summary Judgment on this issue must be denied.

II. PCPC AGAIN MISAPPLIES THE CHOICE-OF-LAW ANALYSIS.

PCPC continues to muddy the water in its Reply as to choice of law by incorrectly stating that "New Jersey and D.C. choice-of-law tests are largely inapplicable because only one factor is known, PCPC's domicile." (Reply at 2.) But contrary to this statement, two other factors that are relevant to choice of law are also known, yet PCPC ignores them: (1) the place where the conduct causing the injury occurred; and (2) the place where the relationship between the parties is centered. An analysis of these factors requires an application of the substantive law of the District of Columbia, and PCPC offers no counter-arguments to Plaintiffs' analysis.

PCPC also incorrectly states that "New Jersey law[] . . . is the law of the forum . . . " (Reply at 2.) In making this argument, PCPC ignores that many of the cases filed against PCPC have designated the District of Columbia for remand; therefore, the District of Columbia is the "forum" for those cases. Moreoever, New Jersey is the "forum" only because this MDL has been assigned to this Court in New Jersey, but Plaintiffs are from virtually every state in the country. Pursuant to the Supreme Court's recent *Bristol Myers* decision, personal jurisdiction over PCPC can exist only in the District of Columbia or New Jersey. Each Plaintiff who is maintaining a claim against PCPC had the right to choose the venue of remand in the Short Form Complaint. It is far too simplistic to say that New Jersey law applies for each Plaintiff. PCPC is improperly forum shopping the law to apply.

Even for cases that have designated New Jersey as the venue for remand, PCPC's only

support is the *Accutane* case,[1] where the choice-of-law analysis was much different. In *Accutane*, the court had to address choice-of-law among cases involving 45 different states. Here, only the laws of the District of Columbia and New Jersey are at issue.

PCPC misses the mark when it argues that "[i]nconsistent results could occur if D.C. law [is] applied to one defendant and New Jersey law applied to others, particularly as to claims asserted against all defendants." (Reply at 2.) In this context, the Court is only addressing claims against PCPC, not multiple defendants. Applying District of Columbia law, as opposed to New Jersey law, is just as efficient and will not lead to inconsistent results as argued by PCPC. Plaintiffs do not dispute that a choice-of-law analysis might be different if there were mixed claims against multiple Defendants, but that's simply not the case here.

Lastly, PCPC misapplies the District of Columbia's "governmental interest" prong of the choice-of-law analysis. The District of Columbia does not have a greater interest in applying the New Jersey Product Liability Act as opposed to its own common law, especially as it relates to the conduct of a District of Columbia corporation. Because the claims against PCPC center in the District of Columbia, the District of Columbia has a greater interest in applying its laws and applying New Jersey law would more significantly frustrate the laws of the District of Columbia.

III. PCPC'S UNTIMELY ATTEMPT TO DISMISS PLAINTIFFS' CLAIMS BASED ON THE DISTRICT OF COLUMBIA ANTI-SLAPP ACT FAILS.

A. PCPC grasps at straws to convince the Court that its motion is timely.

PCPC did not timely file a Special Motion to Dismiss under the District of Columbia Anti-SLAPP Act. Contrary to PCPC's assertions, the time limit contained in the Act cannot be extended by court order. (Pls.' Opp. at 19.) Case Management Order No. 2 did not, and could

[1] As a New Jersey appellate case, *Accutane* is not binding on cases that have designated the District of Columbia as the venue for remand.

not, extend the time for filing a Special Motion to Dismiss under the Act as PCPC argues in its Reply.

PCPC also failed to "expressly preserve[] the defense[]" (Reply at 18) in its First and Second Motion to Dismiss because it did not properly adhere to the time requirement of the Act. PCPC did not raise the Anti-SLAPP defense in its Second Motion to Dismiss filed in 2017, which was the only motion to dismiss ever briefed.[2] Instead, PCPC stated that "[a]fter the jurisdictional issues are resolved, PCPC intends to file a motion for summary judgment based on the First Amendment, the Noerr-Pennington doctrine, anti-SLAPP statutes, and other grounds." (ECF No. 256-1 at 1.) This does not comport with the 45-day time limit in the Act. PCPC should have raised the Anti-SLAPP arguments then, and by failing to do so it waived its right to do so.

Further, even if Plaintiffs "caused any delay[]"or "PCPC would be prejudiced if denied the ability to raise the defense[,]" (Reply at 18), these are not valid bases to toll the 45-day time limit in the Act. [3]There are no exceptions that extend the time to file a Special Motion to Dismiss under the Act.

B. The decision in *Simpson* was incorrect and based on a limited factual record and incomplete briefing.

In its Reply, PCPC argues that this Court should blindly rely on the decision in *Simpson*, despite it being decided nearly four years ago without all the facts now available to the Court.[4]

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[2] PCPC's First Motion to Dismiss was mooted by the filing of Plaintiffs' Amended Master Complaint.

[3] PCPC simply could have timely filed its Motion and then have entered into a stay if there was an issue about when the Motion should be briefed. But it did not file in time, and cannot now shift the blame for its failure to the Plaintiffs, where PCPC was in control of whether or not to file in the first instance.

[4] This argument is reminiscent of the argument made by the Johnson defendants that this case has no merit because a similar case in New Jersey state court before Judge Nelson Johnson was dismissed. Contrary to that argument, Plaintiffs have produced substantially different fact

While PCPC may be correct that the general allegations in *Simpson* and in the MDL are ***similar***, there was absolutely no factual record in the *Simpson* case at the time of briefing. For example, only a handful of the 130 exhibits attached to Plaintiffs' Opposition were available to the plaintiff in *Simpson* at the time of briefing the motion. As for arguments, the plaintiff in *Simpson* did not address the likelihood of success on the merits (the second prong of the Anti-SLAPP analysis) because further discovery was needed. Here, Plaintiffs have had discovery, produced supporting evidence, and briefed this issue. (*See* Pls.' Opp. at Section III.)

Lastly, PCPC takes issue with Plaintiffs' distinguishing *Simpson* because the plaintiff in *Simpson* "did not appeal . . . [and therefore] argument that *Simpson* misapplied the statute is suspect." (Reply at 19.) However, the decision by the plaintiff in *Simpson* to forego an appeal has no bearing on the Court's analysis in the present matter.

IV. PCPC MISTATES EVIDENCE RELATED TO COMMON LAW CLAIMS.

A. PCPC's Negligence Arguments Fail.

Although PCPC is a trade association that does not sell cosmetics, PCPC still owed a duty to the Plaintiffs. Having voluntarily undertaken a duty to Plaintiffs, the factual evidence shows PCPC breached this duty causing Plaintiffs' injuries.

1. PCPC Misstates the Evidence That It Owed a Duty to Plaintiffs.

Courts have found that trade associations have taken sufficient actions to owe a duty to users of member products. *See Snyder v. Am. Ass'n of Blood Banks*, 676 A.2d 1036, 1055 (N.J. 1996) (holding that trade association's commitment to public health does not immunize them from liability for negligent discharge of their obligations); *Meneely v. S.R. Smith, Inc.*, 5 P.3d 49

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and expert evidence to support their claims. Moreover, the case in state court is on appeal along with a request to supplement that record in light of the new evidence developed in this MDL.

(Wash. Ct. App. 2000) (finding that a trade association that sets safety standards owes a duty to the ultimate consumer). In addition, some courts have found that trade associations have an affirmative duty under the voluntary rescue doctrine when the association "gratuitously assumes a duty to act on behalf of another and fails to act with due care in performing that duty," *Meneely*, 5 P.3d at 856. Similar to *Snyder* and *Meneely*, PCPC, working with the industry, established the required safety testing standards for the cosmetic industry. PCPC also instituted a Consumer Commitment Code to be signed by their members attesting to adherence to the standards set by PCPC. This code was equivalent to a seal certifying compliance with PCPC's established standards of safety (https://www.personalcarecouncil.org/science-safety/consumer-commitment-code/).

Even if setting the talc safety standards and instituting this code was all PCPC did, this alone would be sufficient to establish that PCPC voluntarily assumed a duty to act but failed to do so with due care in failing to warn the Plaintiffs of the hazards which may result from cosmetic talc use and in perpetuating the use of talc products even in the face of its dangerous and toxic properties. In addition to creating the industry accepted safety standard, PCPC created the definition of cosmetic talc and the government, industry, and Plaintiffs relied upon this standard definition.

PCPC has emphasized for years that its CIR program is the linchpin for voluntarily, self-regulating the cosmetic industry. (*See* Pls.' Opp. at 28.) Indeed, PCPC relied upon its CIR program to substantiate the safety of talc products since there is no pre-market approval. Member manufacturers use PCPC's CIR as a stamp of approval for the safety of the ingredients in their products. The CIR's flawed review of talc further created a false sense of safety of talc and talc based body powders.

2. PCPC Mischaracterizes How Its Actions Caused Plaintiffs' Injuries.

As PCPC voluntarily undertook a duty of care to the Plaintiffs, PCPC breached its duty causing Plaintiffs' injuries. PCPC failed to exercise reasonable care by failing to amend its testing standards, by continuing to characterize cosmetic talc as containing zero asbestos fibers, and rubber stamping the proclaimed safety of talc through PCPC's own CIR program, all the while knowing the evidence was to the contrary.

By failing to amend its inadequate testing standard and definition of cosmetic talc, PCPC allowed industry members to claim, and Plaintiffs to believe, that cosmetic talc and talc-based powders contain no carcinogenic or possibly carcinogenic constituents. By conducting and publishing an inadequate, biased review of talc in order to substantiate the safety of talc, PCPC and its members created and promoted a seal of approval for talc and talc based products. Both instances have allowed these dangerous products at issue to remain on the market for far longer than the products should have been.[5] By enabling these products to remain on the market, PCPC increased the risk of injury to the general public and, as a result of PCPC's breach of its duty, Plaintiffs developed ovarian cancer. For these reasons, Plaintiffs' negligence claims present genuine disputes of material fact.

B. PCPC's Arguments on Fraud Fail.

PCPC argues that Plaintiffs' evidence does not satisfy the elements for a fraud claim. However, PCPC's arguments demonstrate an issue of material fact that warrants denial of its motion for summary judgment.

Defendant first claims that its activities were related to "genuine lobbying activities,"

[5] Plaintiffs note that on May 19, 2020, Johnson & Johnson announced that it would discontinue the sale of talc-based Johnson's Baby Powder in the United States and Canada.

citing to the same case cited by Plaintiffs for the proposition that PCPC is ***not*** exempt from liability. *See U.S. v. Philip Moris USA Inc.*, 566 F.3d 1095 (D.C. Cir. 2009). In doing so, PCPC ignores that the majority of these activities were not "lobbying activities" at all. Whenever citizens or scientists published on the safety of talc, PCPC repeatedly developed response statements that it released to the public touting both the safety of talc or the absence of asbestos from talc. These statements were also sent out to its member organizations, including Johnson & Johnson and Imerys, and used by its members to respond to any negative press or studies. Such activities are not at all government facing or founded in lobbying activities.

In a September 17, 1997 letter to Johnson & Johnson, PCPC's consultant and expert Dr. Alfred Wehner goes through a number of the statements that PCPC made over the years about talc. He begins by including how PCPC's 1992 response statements on talc translocation were inaccurate, its statements on industrial exposure to talc and cancer in industrial settings were "outright false," and finishing with a critique of its 1994 statement made after the PCPC sponsored talc workshop. Dr. Wehner states:

> "The workshop concluded that, although some of these studies suggest a weak association might exist, when taken together the results of the studies are insufficient to demonstrate and real association." This statement is also inaccurate, to phrase it euphemistically. At that time there had been about 9 studies (more by now) published in the open literature that did show a statistically significant association between hygienic talc use and ovarian cancer. Anybody who denies this risks that the talc industry will be perceived by the public like it perceives the cigarette industry; denying the obvious in the face of all evidence to the contrary.[6]

PCPC obsufucates the issue by arguing there has been no authoritative finding on talc,

[6] JNJ000040596. One of the phrases in this document was originally referenced in Plaintiffs Opposition and was inadvertently cited to as Exhibit 99 with bates number JNJ000011933. JNJ000040596 should be substituted for Exhibit 99 in the Opposition as well as used here.

and that none of the Plaintiffs' experts had published opinions on talc causing ovarian cancer prior to litigation. PCPC's argument should be rejected as nothing more than a disguised *Dabuert* challenge of Plaintiffs' experts. The Court has exhaustively assessed Plaintiffs' experts opinions, and has ruled on their admissibility.

PCPC also claims that Plaintiffs have offered no evidence that PCPC knew conclusively that talc causes ovarian cancer and that the issue of whether talc causes ovarian cancer is still hotly contested. But PCPC's own definition of safety states that "'[s]afe' or 'safety' means ***no evidence*** in the available information that demonstrates or suggests reasonable grounds ***to suspect a hazard to the public*** under the conditions of use that are now current or that might reasonably be expected in the future[.]" (CIR Procedures at 2, attached as **Exhibit 1** (emphasis added).) Further, C.F.R. 740.1 states that "the label of a cosmetic product ***shall*** bear a warning statement whenever necessary or appropriate to prevent a health hazard that ***may be associated*** with the product." (emphasis added). There is substantial evidence that PCPC has known for decades that there was evidence that talcum powder products were associated with a health hazard. PCPC's argument that findings must be conclusive for it to be liable run counter to its stated public position.

Lastly, PCPC claims Plaintiffs have shown no evidence that PCPC knew that talc contained asbestos. However, evidence shows PCPC developed the actual asbestos testing standards for talc and knew the standards it created were not sufficiently sensitive so that asbestos would not be detected in talcum powder. Plaintiffs' experts have undergone a *Daubert* challenge on this issue and will testify to the presence of asbestos in talc, raising a genuine issue at to what PCPC knew and when. PCPC knew or should have known that its statements about

talc and asbestos were false, but made false representations and offered conclusions for the sole purpose of deceiving the public and regulatory authorities in order to keep talc on the market.

CONCLUSION

For these reasons, as well as the reasons discussed in Plaintiffs' Opposition, the Court should deny PCPC's Motion for Summary Judgment.

Dated: June 30, 2020

Respectfully submitted,

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Exhibit 1

Cosmetic Ingredient Review Procedures & Support to the Expert Panel for Cosmetic Ingredient Safety

September 2019

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Part A -- General

Section 1. Definitions.

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) "Cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that it shall not include soap.

(c) "Cosmetic ingredient" means any chemical substance used as a component in the manufacture of a cosmetic product, but shall not include a proprietary mixture.

(d) "Cosmetic product" means a finished cosmetic the manufacture of which has been completed.

(e) "Commercial distribution" of a cosmetic product means annual gross sales in excess of $1,000 for the product.

(f) "Chemical description" means a concise definition of the chemical composition using standard chemical nomenclature so that the chemical structure or structures of the components of the ingredient would be clear to a practicing chemist. When the composition cannot be described chemically, the substance shall be described in terms of its source and processing.

(g) "Flavor" means any natural or synthetic substance or substances used solely to impart a taste to a cosmetic product.

(h) "Fragrance" means any natural or synthetic substance or substances used solely to impart an odor to a cosmetic product.

(i) "Cosmetic Ingredient Review (CIR)" means the Cosmetic Ingredient Review program conducted pursuant to these procedures.

(j) "Council" means the Personal Care Products Council.

(k) "Executive Director" means the Executive Director of the Cosmetic Ingredient Review, who shall have the authority and responsibilities established in Section 12 of these procedures.

(l) "Expert Panel" means the Expert Panel for Cosmetic Ingredient Safety, which shall be established and shall have the authority and responsibilities established in Part C of these procedures and shall conduct the Cosmetic Ingredient Review program in accordance with the procedures established in Part D of these procedures.

(m) "Safe" or "safety" means no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the public under the conditions of use that are now current or that might reasonably be expected in the future, e.g., a low incidence of minor adverse reactions (as shown in animal or human testing or product experience). Such information includes, but is not limited to, the chemical structure of the ingredient, published and unpublished tests on the ingredient and products containing the ingredient, significant human experience on products containing the ingredient during marketing, and information on similar or related substances. A lack of information about an ingredient shall not be sufficient to justify a determination of safety.

(n) "Conditions of use" for an ingredient or product include (1) the amount of an ingredient used in a product, (2) the intended and reasonably foreseeable areas of use (e.g., use that is subject to

ingestion or inhalation or contact with mucous membranes or is in the area of the eye), and (3) directions for use and against misuse in labeling.

(o) "Reserved," when placed at any section heading or sub-heading, means the section or sub-section was deleted.

Section 2. Purpose of the Cosmetic Ingredient Review.

The purpose of the Cosmetic Ingredient Review is to determine those cosmetic ingredients for which there is a reasonable certainty in the judgment of competent scientists that the ingredient is safe under its conditions of use.

Section 3. Interpretation and Amendment of Procedures.

(a) If any dispute arises as to the proper interpretation or application of these procedures, a majority vote of the Steering Committee shall be final and binding with respect to such matter.

(b) These procedures may be amended by a two-thirds vote of the Steering Committee, with the approval of the Council Board of Directors. The Executive Director shall give public notice of any amendment of these procedures.

Part B -- The Cosmetic Ingredient Review Steering Committee and Staff

Section 10. Organization of the Cosmetic Ingredient Review.

(a) General policy and direction for the Cosmetic Ingredient Review shall be given by a Steering Committee. Any matter before the Steering Committee shall be decided by a majority vote of the members present at the time except where otherwise specifically provided in these procedures. The Steering Committee shall consist of the following members:

(1) The President and CEO of the Council, who shall serve as the Chair of the Steering Committee. The Chair may elect the Council's COO to serve as proxy.

(2) A dermatologist, who shall represent the American Academy of Dermatology.

(3) A toxicologist, who shall represent the Society of Toxicology.

(4) The Chair of the Council's CIR Science and Support Committee.

(5) The Council Executive Vice President for Science.

(6) A consumer representative, who shall represent the Consumer Federation of America.

(7) The Chair of the Expert Panel for Cosmetic Ingredient Safety.

(b) The CIR staff shall consist of an Executive Director who shall report to the CIR Steering Committee. The Executive Director may in turn utilize such other personnel as is necessary and appropriate to carry out their authority and responsibilities established in Section 12 of these procedures.

Section 11. Separation and Independence of the CIR Staff.

(a) The CIR staff shall be employees of, or consultants to, the Council but shall be separate and independent from the Council staff. No person on the Cosmetic Ingredient Review staff may also serve on the Council staff. The CIR staff may obtain supplies and services through the central

facilities of the Council. Contact between the CIR staff and Council staff shall be kept to the minimum necessary to conduct the affairs of the CIR efficiently and effectively. Council staff shall be treated by the CIR staff the same as any other member of the public.

(b) The CIR staff shall follow all personnel policies and procedures established in the Council Procedures Manual, except that the Executive Director shall be responsible for all required approvals within the authority granted under Section 12 of these procedures.

Section 12. Executive Director.

(a) The Executive Director shall be appointed by the Chair of the Steering Committee, with the approval of the Chair of the Council Board of Directors and the Chair of the Council Scientific Advisory Committee Executive Committee.

(b) The Executive Director shall hire and direct the activities of the CIR staff in order to implement these procedures effectively and efficiently. The Executive Director shall report to and be subject to the direction and control of the Steering Committee with respect to policy and budget within the following limitations:

(1) The Council Board of Directors shall determine the budget and personnel limits for the CIR.

(2) The Chair of the Steering Committee shall periodically review CIR expenditures (e.g., document reproduction, communications, accounting, and office space expenditures) to determine that they are within the budget.

(3) All CIR contracts and capital expenditures shall be reviewed and approved by the Chair of the Steering Committee prior to execution.

(4) All CIR office supplies shall be obtained through Council central purchasing unless otherwise approved by the Chair of the Steering Committee.

(c) The Executive Director shall have authority and responsibility for daily administration of the CIR staff and Expert Panel. This shall include receipt of all documents submitted by any interested person with respect to the CIR, distribution of all data and information to the Expert Panel, arranging for all aspects of the meetings of the Expert Panel, including public notice thereof, serving as secretary to the Steering Committee, and all similar administrative functions.

Part C -- The Expert Panel for Cosmetic Ingredient Safety and Liaison Representatives

Section 20. Members of the Expert Panel and Liaison Representatives.

(a) Members of the Expert Panel shall possess the following qualifications:

(1) Members shall possess expertise relevant to the review of the safety of cosmetic ingredients. They shall have diverse professional education, training, and experience so that the Expert Panel will reflect a balanced composition of sufficient scientific expertise to handle the issues that come before it.

(2) Members shall be required to meet the same conflict of interest standards as are applicable under Federal Law to special government employees.

(b) A member shall be appointed to the Expert Panel for a term of six years and may be reappointed for additional terms as appropriate. These limitations shall not apply to the Chair.

(c) An Expert Panel member may be removed from membership by the Steering Committee for good

cause. Good cause shall include but not be limited to excessive absenteeism from Expert Panel meetings, a demonstrated bias which interferes with the ability to render objective advice, or failure to abide by these procedures.

(d) There shall ordinarily be nine members of the Expert Panel, each member having an equal vote. The Expert Panel shall begin to function, and may continue to function, as long as there are not less than seven members.

(e) Liaison representatives shall be selected by the interested organizations as provided in Section 22 of these procedures. Technical expertise with the subject matter with which the Expert Panel is involved shall not be a requirement. A liaison representative shall continue to serve for the duration of the Expert Panel or until they resign.

Section 21. Nominations and Selection of Members of the Expert Panel.

(a) The Executive Director shall give public notice requesting nominations for members of the Expert Panel. The notice shall invite the submission of nominations for members from any interested individual as well as from consumer, industry, and professional organizations, within 90 days of such notice.

(b) Any interested person may nominate one or more qualified person(s) as a member of the Expert Panel. Nominations shall include a complete curriculum vitae of the nominee, and shall state that the nominee is aware of the nomination, is willing to serve as a member of the Expert Panel, and appears to have no conflict of interest which would preclude membership on the Expert Panel.

(c) Members of the Expert Panel shall serve as individuals and not as representatives of any group or organization which nominated them or with which they may be affiliated.

(d) The Steering Committee shall appoint the members of the Expert Panel from among those who have been nominated, after consultation with the Consumer Liaison Representative and the FDA Liaison Representative. Appointment shall be decided by a majority vote of all current members of the Steering Committee. Appointment shall be on the basis of scientific competence, expertise in an area relevant to the CIR, balance of scientific disciplines within the Expert Panel, willingness to devote sufficient time and energy to the review, and the lack of any disqualifying conflict of interest.

(e) All data and information relating to the nomination and selection of the members of the Expert Panel shall be maintained by the Executive Director in a confidential file.

(f) Vacancies in the membership of the Expert Panel shall be filled by the Steering Committee either from prior nominations or in the same way that members are initially nominated and selected.

Section 22. Selection of Liaison Representatives to the Expert Panel.

(a) The Executive Director shall request that each of the following interests designate a liaison representative to the Expert Panel:

(1) The Food and Drug Administration, in accordance with the provisions of 21 C.F.R. 10.95(d).

(2) The Consumer Federation of America, representing consumer interests.

(3) The Council.

(b) Liaison representatives to the Expert Panel shall be limited to three persons, one representing each of the listed interests. Those interests may, however, designate different liaison representatives for purposes of the review of different categories of cosmetic ingredients or similar considerations. At

no time may there be more than one liaison representative to the Expert Panel from any one of the interests listed in Section 22(a) of these procedures with respect to any specific cosmetic ingredient.

(c) Because liaison representatives for government, consumer, and industry interests have no vote, their selection shall be solely by the interests they represent and shall be without regard to the conflict of interest principles for special government employees that are applicable to the members of the Expert Panel.

(d) Vacancies in the liaison representatives to the Expert Panel shall be filled in the same way that liaison representatives are initially selected.

Section 23. Rights and Responsibilities of Liaison Representatives to the Expert Panel.

(a) A liaison representative to the Expert Panel selected to represent and serve as a liaison with interested individuals, associations, and organization, shall have the same rights as members of the Expert Panel except that:

A liaison representative shall not vote on any matter before the Expert Panel.

(b) A liaison representative of the Expert Panel is subject to, and shall abide by, all aspects of these procedures and any rules and regulations adopted by the Expert Panel pursuant to section 32 of these procedures.

(c) It is the responsibility of the liaison representative to the Expert Panel to represent the government, consumer, and industry interests in all deliberations.

(1) The consumer and industry liaison representatives do not represent any particular organizations or groups, but rather represent all interested persons within the class which the liaison is selected to represent. Accordingly, any interested person within the class represented by that liaison representative shall have access to all written statements or oral briefings related to the Expert Panel prepared by the liaison representative for distribution to any person outside the Expert Panel.

(2) Liaison representatives shall review all official Expert Panel minutes to assure their completeness and accuracy.

(3) The liaison representative shall act as a liaison with and conduit between the Expert Panel and the interested persons whom the liaison represents, and shall transmit requests for information from the Expert Panel and relevant data, information, and views to the Expert Panel. The liaison shall take the initiative in contacting interested persons whom the liaison represents, to seek out relevant data, information, and views, and to relate the progress of the Expert Panel.

(4) The industry liaison representative shall represent all members of the industry, and not any particular association, company, product, or ingredient. If a matter comes before the Expert Panel that directly or indirectly affects the company which employs the industry liaison representative, the liaison need not be absent during the discussion or decline to participate in the discussion. The industry liaison representative shall not discuss the liaison's company's position as such, but may discuss any matter in general terms. All presentations and discussions of scientific data and their interpretation on behalf of a company shall occur in open session.

(5) A liaison representative to the Expert Panel shall not make any presentation to the Expert Panel during a hearing conducted by the Expert Panel.

(6) Although a liaison representative is serving in a representative capacity, that person shall exercise restraint in performing this function and shall not engage in unseemly advocacy or attempt to exert undue influence over members of the Expert Panel.

(d) A liaison representative to the Expert Panel may be removed by the Steering Committee for failure to comply with the provisions of this section or the other sections of these procedures. In the event of removal of a liaison representative, the interests which had been represented shall be requested to select a new liaison representative.

Section 24. Reimbursement of Expert Panel Members.

(a) All members of the Expert Panel and liaison representatives shall be reimbursed for time away from their careers to participate in preparation and participation in proceedings, for their travel expenses, and for all other out-of-pocket expenses, unless such reimbursement is waived.

(b) An Expert Panel member or liaison representative, notwithstanding the primary residence, while in attendance at meetings of the Expert Panel, will be reimbursed whether the meetings are held in the city of residence or elsewhere.

(c) An Expert Panel member or liaison representative who participates in a specific assignment for the Expert Panel, at the request of the CIR, will be reimbursed at an hourly rate when performing work at home, place of business, or elsewhere, and at a daily rate when required to travel outside of the commuting area to perform the assignment.

(d) Reimbursement for time while in travel status is authorized when an Expert Panel member or liaison representative has ordinary pursuits interrupted for the substantial portion of an additional day beyond the day or days on which the services are performed, and as a consequence, sustains a loss in regular compensation. This applies on weekends and holidays if the Expert Panel member or liaison representative suffers a loss in income that would otherwise be earned on that day. For travel purposes, a substantial portion of a day is defined as 50 percent of the working day, and the traveler will be paid at a daily rate.

Section 25. Chair of the Expert Panel.

(a) The Steering Committee shall select the Chair of the Expert Panel from among the members.

(b) The Chair of the Expert Panel shall have the authority to conduct hearings and meetings, including the authority to adjourn any hearing or meeting whenever the Chair determines adjournment to be advisable, to discontinue discussion of a particular matter, to conclude a meeting in accordance with Section 36 of these procedures, or to take any other action in furtherance of a fair and expeditious hearing or meeting.

Section 26. Ex Parte Contacts with the Expert Panel.

(a) There shall be no ex parte contacts between the members of the Expert Panel and anyone other than a liaison representative to the Expert Panel or a member of the CIR staff with respect to any matter relating to the CIR, nor shall any substantive matter relating to an ingredient review be discussed outside of the public Expert Panel meetings, except that:

(1) The Steering Committee or the Chair of the Steering Committee may meet with the Expert Panel or any members thereof or any liaison representatives to discuss the work of the Expert Panel.

(2) A member of the Expert Panel may initiate discussion with any other scientist for the purpose of obtaining data, information, or views with respect to any scientific issue.

(b) If a person initiates an ex parte contact with a member of the Expert Panel other than as permitted by paragraph (a) of this section, such member shall refer such person to the CIR Executive Director for advice on the procedures for submission of data, information, and views to the Expert Panel.

Section 27. Compilation of Background Materials for Members of the Expert Panel and Liaison Representatives.

The Executive Director shall prepare and provide to Expert Panel members and liaison representatives a complete compilation of background materials bearing upon their duties and responsibilities.

Part D -- Ingredient Review Procedures

Section 29. Ingredients Which May Be Excluded from Review by the Expert Panel.

To minimize duplication of effort, the inclusion and priority of cosmetic ingredients which are also subject to other existing safety reviews shall be determined as follows, except that any specific ingredient the review of which may otherwise be deferred shall nonetheless be included at the discretion of the Expert Panel when other chemically related or otherwise conveniently grouped ingredients are considered, and except with respect to any specific ingredient for which the Expert Panel has assigned a special priority for good cause with the approval of the Steering Committee.

(a) Color Additives. Color additives may be excluded from the assessment because their safety is determined under 21 C.F.R. Part 71.

(b) OTC Drug Active Ingredients. The Expert Panel may exclude from evaluation a cosmetic ingredient which is also used as an active ingredient in an OTC drug, and thus is subject to review under the Food and Drug Administration OTC Drug Review established in 21 C.F.R. Part 330, until after the final monograph for the relevant OTC drug category (or, if there is more than one, the last relevant OTC drug category) is promulgated by the Food and Drug Administration and shall then determine whether all safety information relevant to cosmetic use of the ingredient was available to the OTC Drug Review and whether the cosmetic use of the ingredient presents any additional safety considerations not adequately covered by the OTC Drug Review. The Expert Panel shall adopt those conclusions of the OTC Drug Review which it concludes adequately cover cosmetic use of the ingredient and shall conduct its own evaluation of those cosmetic uses not adequately covered by the OTC Drug Review.

(c) Food Flavors. The Expert Panel may exclude from evaluation a cosmetic flavor ingredient which is also used as a flavor in food, and thus is subject to review under the FASEB-FDA review of flavor ingredients which are GRAS or food additives described in Part II of the Federal Register of July 26, 1973 (38 F.R. 20036 et seq.) and Part II of the Federal Register of September 23, 1974 (39 F.R. 34172 et seq.), or defer evaluation until after the final regulation for the ingredient is published by the Food and Drug Administration and shall then determine whether all safety information relevant to cosmetic use of the ingredient was available to the FASEB-FDA review and whether the cosmetic use of the ingredients presents any additional safety considerations not adequately covered by the FASEB-FDA review. The Expert Panel shall adopt those conclusions of the FASEB-FDA review which it concludes adequately cover cosmetic use of the ingredient and shall conduct its own evaluation of those cosmetic uses not adequately covered by the FASEB-FDA review.

(d) GRAS Food Ingredients. The Expert Panel may exclude from evaluation a cosmetic ingredient which is also used as an ingredient in a food on the basis that it has been determined to be GRAS or subject to a prior sanction and thus is subject to review under the FASEB-FDA review described in Part II of the Federal Register for July 26, 1973 (38 F.R. 20036 et seq.) and Part II of the Federal Register for September 23, 1974 (39 F.R. 34172 et seq.), or defer evaluation until after the final

regulation is promulgated for the ingredient by the Food and Drug Administration and shall then determine whether all safety information relevant to cosmetic use of the ingredient was available to the FASEB-FDA review and whether the cosmetic use of the ingredient presents any additional safety considerations not adequately covered by the FASEB-FDA review. The Expert Panel shall adopt those conclusions of the FASEB-FDA review which it concludes adequately cover cosmetic use of the ingredient and shall conduct its own evaluation of those cosmetic uses not adequately covered by the FASEB-FDA review.

(e) Food Additives. In evaluating a cosmetic ingredient which is also used as a food additive, and thus is subject to a food additive regulation promulgated by the Food and Drug Administration in 21 C.F.R. Part 171, the Expert Panel shall review the food additive petition and all related documents which the Food and Drug Administration makes available to determine whether all safety information relevant to cosmetic use of the ingredient was available to the Food and Drug Administration and whether the cosmetic use of the ingredient presents any additional safety considerations not adequately covered by the Food and Drug Administration approval of the food additive regulation. The Expert Panel shall adopt those conclusions of the Food and Drug Administration approval which it concludes adequately cover cosmetic use of the ingredient and shall conduct its own evaluation of those cosmetic uses not adequately covered by the Food and Drug Administration approval.

(f) Fragrance Ingredients. Fragrance ingredients may be excluded from evaluation by the Expert Panel if their safety is being determined by the Research Institute for Fragrance Materials (RIFM). A fragrance ingredient is defined as an ingredient that is only known to function as a fragrance in cosmetic formulations.

(g) Food and Drug Administration Regulations. All matters which are the subject of a final regulation promulgated by the Food and Drug Administration may be excluded from assessment.

(h) New Drug Applications. In evaluating a cosmetic ingredient which is also used as an inactive or active ingredient in an OTC or prescription drug for which the Food and Drug Administration has at any time approved a New Drug Application, the Expert Panel shall review all related documents which the Food and Drug Administration makes available to determine whether all safety information relevant to cosmetic use of the ingredient was available to the Food and Drug Administration and whether the cosmetic use of the ingredient presents any additional safety considerations not adequately covered by the Food and Drug Administration action on the New Drug Application. The Expert Panel shall adopt those conclusions of the Food and Drug Administration action which it concludes adequately cover cosmetic use of the ingredient and shall conduct its own evaluation of those cosmetic uses not adequately covered by the Food and Drug Administration action.

Section 30. Annual Ingredient Priority List and Review Process

(a) The Expert Panel shall develop an annual priority list for the review of ingredients presently used in commercially distributed cosmetic products. The annual priority list shall be based upon the frequency of use (i.e., the number of different products in which an ingredient is used) as determined from the Food and Drug Administration's Voluntary Cosmetic Registration Program (VCRP). Within the annual priority list, ingredients may be further prioritized based on toxicological considerations. Closely-related or otherwise conveniently grouped ingredients shall be grouped together whenever appropriate.

(1) The annual list shall include at least as many ingredients as is reasonably expected to be reviewed during the year, but it is not necessary to prioritize all ingredients in the VCRP.

(2) Cosmetic ingredients which are also subject to other existing safety reviews shall be handled pursuant to Section 29 of these procedures.

(b) A draft annual priority list shall be made publicly available by June 1 of the preceding year, and 60 days will be provided for public comment.

(c) The Expert Panel shall review all comments received on the draft annual priority list, make any revisions it deems appropriate, and adopt a final annual priority list by October 31. The final annual priority list shall determine the order in which cosmetic ingredients are reviewed under the CIR for that year. The issuance of the final annual priority list shall be accompanied by a call for unpublished data for those ingredients expected to be reviewed in the coming year.

(d) The Expert Panel may at any time revise the final annual priority list to add new ingredients or to revise the priority of existing ingredients. The Expert Panel may, on its own initiative, or at the request of the Chair of the Steering Committee or FDA, or in response to public comment, assign a special priority for and undertake a review of any ingredient(s) that has been identified as deserving expedited review for use in cosmetics.

(e) On the basis of the annual priority list, the Executive Director shall develop or obtain a Scientific Literature Review for each cosmetic ingredient (and wherever appropriate closely related ingredients that can be reviewed together). The Scientific Literature Review shall consist of a bibliography of relevant scientific literature, study reports that have been submitted by interested parties, a description of each literature reference or submitted study report, and a summary of the information for each ingredient or closely related group of ingredients. The Executive Director may either contract for the preparation of each Scientific Literature Review or prepare it internally. Initiation of a Scientific Literature Review for an ingredient(s) shall be accompanied by a public announcement with a second request for relevant unpublished data and information.

(f) Information and data which will be of value to CIR and the Expert Panel include but are not limited to:

(1) The INCI adopted name of the cosmetic ingredient(s) involved, physico-chemical properties, chemical structure, the method of manufacture, ingredient specifications including purity, and characterization of complex mixtures (e.g., botanicals).

(2) Use information from the VCRP and concentration of use obtained from surveys completed by the Personal Care Products Council, or directly from suppliers of the ingredient or companies reporting use of the ingredient.

(3) Non-human data.

(A) Animal and in vitro data on:

(i) The individual cosmetic ingredient.

(ii) Mixtures containing the individual cosmetic ingredient.

(iii) Cosmetic products or other products containing the individual cosmetic ingredient as one component.

(iv) Closely related structural analogues.

(B) Other relevant safety information.

(i) Structure-activity modeling data.

(ii) Results of computational methods.

(iii) Application of risk assessment tools, such as Threshold of Toxicological Concern analysis, when appropriate.

(4) Human data.

(A) Human data on the individual cosmetic ingredient.

(B) Human data on mixtures containing the individual cosmetic ingredient.

(C) Human data on cosmetic products or other products containing the individual cosmetic ingredient as one component, including results of significant human experience during marketing.

(5) Conditions of use.

(A) A statement that the ingredient is or is not used in a cosmetic which falls into the following general use classifications.

(i) Eye area use.

(ii) Subject to incidental ingestion.

(iii) Subject to incidental inhalation.

(iv) Mucous membrane use.

(v) All other uses (e.g., skin, hair, and nails).

(B) A statement indicating the use classifications for each of the products in which the ingredient is used by the manufacturer or distributor, following the classification system of the Food and Drug Administration (Form FD-2512 (Cosmetic Product Ingredient Statement), 21 C.F.R. 720.4(c)).

(C) Information on any other relevant conditions of use (e.g., directions for use and against misuse).

(6) A summary of the data and views setting forth the rationale for the conclusion that the ingredient is or is not safe for its intended use.

(g) Upon public availability of a Scientific Literature Review all interested persons shall be provided 60 days to submit to the Executive Director data, information, and views relevant to the safety of the cosmetic ingredient involved. A person may submit any of information without identifying the source of the information.

(h) Upon expiration of the time permitted for receipt of all pertinent data and information, the CIR staff shall prepare a compilation of relevant data and information for presentation to the Expert Panel. That compilation shall include:

(1) A Draft Report

(2) All comments received on the Scientific Literature Review.

(3) All submissions of data and information not contained in the Scientific Literature Review.

(i) The Expert Panel may, at its discretion, accept submissions and new data relating to any ingredient at any time prior to the issue of a final report on that ingredient.

(j) An ingredient (or a group of closely related ingredients) shall be reviewed as described in this section.

(1) Upon presentation of all pertinent data and information to the Expert Panel pursuant to paragraph (h) of this section, an ingredient shall be considered to be under review by the Expert Panel. An ingredient shall remain under review by the Expert Panel until the Expert Panel issues a final report on it pursuant to Section 45 of these procedures.

(2) If the Expert Panel concludes that the available data and information are insufficient to determine whether the ingredient, under each relevant condition of use, is either safe or not safe, it shall decide the type of additional data or information required. Any such decision shall be set forth fully in the minutes of the Expert Panel meeting.

(A) Upon public availability of the summary of any such meeting pursuant to Section 51 of these procedures, the Executive Director shall give public notice of any such decision.

(B) Within 60 days after such public notice, any interested person may inform the Expert Panel that work adequate and appropriate to resolve the questions raised about the ingredient will be undertaken.

(C) A progress report on any work undertaken pursuant to such a commitment shall be provided to the CIR as determined by the Expert Panel.

(D) If such a commitment is undertaken, the ingredient shall remain under review by the Expert Panel and the Expert Panel shall defer preparation of a Tentative Report pursuant to Section 44 of these procedures and a Final Report pursuant to Section 45 of these procedures until completion of the work involved, unless the Expert Panel determines that the work is not being pursued promptly and diligently or that interim results indicate a reasonable likelihood that a health hazard exists.

(E) Upon completion of the work undertaken pursuant to such a commitment, the Expert Panel may conclude either that the available data and information remain insufficient to make a safety determination or that there are now sufficient data and information for such a determination. Where there remain insufficient data and information for a determination, the procedure established in paragraph (j)(2) shall be followed. Where there are sufficient data and information to make a determination, the Expert Panel shall review all available data and information and shall issue a Tentative Report pursuant to Section 44 of these procedures and a Final Report pursuant to Section 45 of these procedures.

(3) If the Expert Panel determines pursuant to paragraph (j)(2) of this section that the available data and information are insufficient to determine such ingredients, under specific conditions of use, as either safe or not safe, and no one undertakes the work to obtain the required data and information in accordance with paragraph (j)(2)(B) of this section, the Expert Panel shall determine that there is a lack of information needed to make a determination that the ingredient is safe under its intended conditions of use and shall issue a Tentative Report pursuant to Section 44 of these procedures and a Final Report pursuant to Section 45 of these procedures.

Section 31. Meetings of the Expert Panel.

(a) The Expert Panel will meet as often and for as long as is appropriate to review the data submitted to it and to prepare a report containing its conclusions and recommendations with respect to the safety of cosmetic ingredients.

(b) The Expert Panel shall convene at the call of the Chair. The Executive Director shall be responsible for giving appropriate notice to all Expert Panel members and liaison representatives, for distributing all pertinent information, for all travel and meeting arrangements, and for similar administrative support.

(c) All Expert Panel meetings shall be held in Washington, D.C., or the immediate vicinity, unless there are sound reasons for a different location.

(d) The Expert Panel may conduct on-site visits relevant to the work of the Expert Panel.

(e) A quorum for the Expert Panel shall be at least seven members (out of the nine voting members) of the Expert Panel. Any matter before the Expert Panel shall be decided by a majority vote of a quorum, except that any Final Report shall be voted upon by all available members of the Expert Panel.

(f) Subject to availability of space, any interested person may attend any portion of any Expert Panel meeting.

(g) Reserved

(h) Any Expert Panel member or liaison representative may take notes during Expert Panel meetings and report and discuss the deliberations of the Expert Panel after a meeting is completed and before official minutes or a report is available, within such rules and regulations as are adopted by the Expert Panel in accordance with Section 32 of these procedures.

Any notes or minutes kept or report prepared by any Expert Panel member or liaison representative shall have no status or affect whatever unless adopted as or incorporated into the official minutes or report by the Expert Panel. It shall be the responsibility of each Expert Panel member and liaison representative to make certain that the official minutes and reports are complete and accurate and fully reflect what happened at any meeting attended.

Section 32. Additional Rules for the Expert Panel.

(a) In addition to the rules established in these procedures, the Expert Panel may adopt additional rules which are not inconsistent with these procedures.

(b) Such additional rules shall be included in the minutes of the meeting when adopted and in the materials compiled pursuant to Section 27 of these procedures and shall be available for public disclosure pursuant to Section 51(a) of these procedures.

Section 33. Consultation by the Expert Panel with Other Persons.

(a) The Expert Panel may consult with any person who may have data, information, or views relevant to any matter pending before the Expert Panel and, with the approval of the Executive Director, may compensate such person and reimburse expenses.

(b) Any interested person may submit to the Expert Panel a written request that the Expert Panel consult with specific persons who may have data, information, or views relevant to any matter pending before the Expert Panel. Such requests shall state why the specified person should be consulted

and, if payment is requested, why the views of that person cannot reasonably be furnished to the Expert Panel by any other means. The Expert Panel may, in its discretion, deny or grant such a request and, if payment is requested, with the approval of the Executive Director, may compensate such person and reimburse expenses.

Section 34. Reserved.

Section 35. Notice of Public Hearing and Meeting of the Expert Panel.

(a) At least fifteen days before any meeting of the Expert Panel, the Executive Director shall give public notice of such meeting.

(b) Such notice shall include:

(1) The date, time, and place of the hearing and meeting.

(2) A list of all agenda items.

(3) Reserved

(4) The time specifically set aside for oral statements by interested persons and for other public participation.

(5) The name, address, and telephone number of the persons specifically responsible for the administrative support for that hearing and meeting.

(6) A statement that written submissions may be made to the Expert Panel at any time pursuant to Section 38 of these procedures.

Section 36. Reserved

Section 37. Administrative Remedies.

Any person who alleges non-compliance by the Expert Panel or the CIR staff with any provision of these procedures may request appropriate relief from the Steering Committee.

Section 38. Written Submissions to the Expert Panel.

(a) Copies of all written submissions for the Expert Panel shall be sent to the Executive Director, unless an applicable public notice specifies otherwise.

(b) At the request of the Expert Panel, the Executive Director may at any time issue a public notice requesting the submission to the Expert Panel of written data, information, and views pertaining to any matter being reviewed by the Expert Panel. Such notice shall specify the format in which the submission shall be made, the number of copies to be submitted, and the time within which submission shall be made.

(c) Any interested person may submit to the Expert Panel, through the Executive Director, written data, information, or views on any matter being reviewed by the Expert Panel. Voluminous data shall be accompanied by a summary. Written submissions shall ordinarily be made at least thirty days prior to the Expert Panel or working team meeting during which they are intended to be considered.

(1) Any such submission shall be distributed to each Expert Panel member and liaison representative, either electronically or at the next Expert Panel meeting, and shall be considered by the Expert Panel in its review of the matter.

(2) The Expert Panel may establish, and shall give public notice of, a cut-off date after which submissions relating to any matter shall no longer be received or considered.

(d) The Executive Director shall provide for the Expert Panel and liaison representatives all scientific data and information relevant to any matter being reviewed by the Expert Panel. Any member of the Expert Panel or liaison representative shall, upon request, also be provided any additional material available to the CIR appropriate for an independent judgment on the matter, e.g., raw data underlying any summary or report.

Section 39. Conduct of a Public Hearing Before the Expert Panel.

(a) For each Expert Panel meeting, the open portion for public participation which constitutes a public hearing shall be at least one hour long unless the public participation does not last that long, and may last for whatever time the Expert Panel Chair determines will facilitate the work of the Expert Panel. The public notice issued pursuant to Section 35 of these procedures shall designate the time specifically reserved for such public hearing, which shall ordinarily be the first portion of the meeting. Further public participation in any open portion of the meeting pursuant to Section 34(b) of these procedures shall be solely at the discretion of the Expert Panel Chair.

(b) Any interested person who wishes to be assured of the right to make an oral presentation at a particular Expert Panel hearing shall so inform the Executive Director, orally or in writing, at least two weeks prior to the Expert Panel meeting.

(1) Such person shall state the general nature of the presentation and the approximate time requested. Whenever possible, all written data and information to be discussed by that person at the Expert Panel hearing shall be furnished in advance to the Executive Director. Such written material shall be forwarded electronically to the Expert Panel members and liaison representatives in advance of the meeting if time permits, and otherwise will be distributed to the Expert Panel members and liaison representatives when they arrive at the meeting. Such distribution shall be undertaken only by the CIR staff unless the Executive Director specifically permits the person making the presentation to distribute such material.

(2) Prior to the Expert Panel hearing, the Executive Director shall determine the amount of time allocated to each person for an oral presentation and the time that oral presentation is scheduled to begin. Each person shall be so informed electronically. Joint presentations may be required by persons with common interests.

(c) The Chair of the Expert Panel shall preside at the hearing and shall be accompanied by other Expert Panel members and liaison representative who shall serve as a panel in conducting the hearing.

(d) Each person may use the allotted time in whatever way the person wishes, consistent with a reasonable and orderly hearing. A person may be accompanied by any number of additional persons, and may present any written data, information, or views for the consideration of the Expert Panel.

(e) If a person is not present at the time specified for the presentation, the persons following will appear in order. An attempt will be made to hear any such person at the conclusion of the hearing. Any interested persons attending the hearing who did not request an opportunity to make an oral presentation shall be given an opportunity to make an oral presentation at the conclusion of the hearing, in the discretion of the Chair, to the extent that time permits.

(f) The Chair, other members of the Expert Panel, and liaison representatives may question any person during or at the conclusion of the presentation. No other person attending the hearing may question a person making a presentation. The Chair may allot additional time to any person when the Chair

concludes that it is justifiable, but may not reduce the time allotted for any person without that person's consent.

(g) Public participants may question an Expert Panel member or a liaison representative only with that person's permission and only about matters before the Expert Panel.

(h) The hearing shall be informal in nature, and the rules of evidence shall not apply. No motions or objections relating to the admissibility of data, information, and views shall be made or considered, but other participants may comment upon or rebut all such data, information, and views. No participants may interrupt the presentation of another participant at any hearing for any reason.

Section 40. Minutes and Reports of Expert Panel Meetings.

(a) A Senior Scientific Analyst, or other designated CIR staff, shall prepare detailed minutes of all Expert Panel meetings based on the full transcripts of the meeting. The accuracy of all minutes, which should highlight all of the salient, substantive transactions of the meeting, shall be approved by the Expert Panel and certified by the Expert Panel Chair at the following Expert Panel meeting.

(b) The minutes shall include:

(1) The time and place of the meeting.

(2) The names of the Expert Panel members, the CIR staff, and the liaison representative, as well as the names and affiliations or interests of public participants attending the meeting.

(3) A copy of or reference to all information made available for consideration by the Expert Panel at the meeting.

(4) A complete and accurate description of matters discussed and conclusions reached.

(5) A copy of or reference to all reports received, issued, or approved by the Expert Panel.

(6) Reserved

(7) The public participation, including a list of members of the public who presented oral or written statements, and those who attended.

Section 41. Transcripts of Expert Panel Meetings.

(a) A transcript or recording is required for all portions of an Expert Panel meeting.

(b) All such transcription or recordings shall be arranged by the Executive Director.

(c) At the discretion of the Expert Panel, minutes of meetings shall be posted on the CIR website.

(d) If a transcript of an Expert Panel meeting is made by the CIR staff, or is made by an interested person and is submitted to the CIR, it shall be included in the record of the Expert Panel proceedings.

(e) Reserved

(f) Any person attending a portion of an Expert Panel meeting may, consistent with the orderly conduct of the meeting, record or otherwise take their own transcript of the meeting.

Section 42. Expert Panel Determinations.

On the basis of all data and information submitted to it, and after following all the procedures established in Section 30(j), the Expert Panel shall determine whether each ingredient, under each relevant condition of use, is safe, or is not safe, or there are insufficient data or information to make a determination that the ingredient is safe under its intended conditions of use. Upon making such a determination, the Expert Panel shall issue a tentative report pursuant to Section 44 of these procedures and a final report pursuant to Section 45 of these procedures.

Section 43. Working Teams of Expert Panel Members.

Working teams of Expert Panel members may be designated to review information, to prepare draft documents, or to undertake other specific assignments for the Expert Panel, subject to the following conditions:

(a) The Chair of the Expert Panel may appoint working teams comprised of from two to four members of the Expert Panel (one of whom may be the Chair of the Expert Panel) to review information about designated ingredients, to prepare draft documents for consideration by the entire Expert Panel, or to perform other specific assignments for the Expert Panel. The Chair of the Expert Panel shall assign a leader for each working team.

(b) A meeting of a working team is not a meeting of the Expert Panel and shall be governed by the procedures established by this Section and not by the procedures applicable to meetings of the Expert Panel.

(c) A working team shall meet at the call of its leader, issued through the Executive Director. A working team may meet in Washington, DC, at another location if that location is more convenient for the working team members and conserves the resources of the CIR, or may meet via electronic means. Liaison representatives shall be advised of all working team meetings and may attend and participate. Anyone may attend working team meetings

(d) Any document distributed by a working team member to other members of the team, including a call for meeting issued by the team leader, shall be distributed through the Executive Director, who shall simultaneously send the document to the liaison representatives. The Executive Director shall maintain a log and copies of all such documents.

(e) A working team may be assisted by the CIR staff, through the Executive Director. The CIR staff shall be responsible for maintaining minutes of all working team meetings.

(f) A document prepared by a working team may be submitted to the Expert Panel by the leader of the working team, through the Executive Director. The Executive Director shall promptly distribute the document to Expert Panel members and to liaison representatives. Such a document should be received by Expert Panel members and liaison representatives at least two weeks before the Expert Panel meeting at which it is to be voted upon or otherwise considered.

(g) A working team document submitted to the Expert Panel is not a document of the Expert Panel unless and until the Expert Panel approves it. The Expert Panel may approve a working team document with or without revisions, may return the document to the working team for additional work consistent with the directions of the Expert Panel and the procedures described above, or may disapprove the document.

(h) Liaison members may describe to their constituencies the substance of a working team document, but may not quote from the document or make it available for reading or reproduction unless and until it is submitted to the Expert Panel and thereby becomes available for public disclosure. When a working team submits a document to the Expert Panel, the document becomes subject to the

provisions of these procedures governing public availability of documents submitted to the Expert Panel and thereby becomes available for public disclosure in accordance with Section 51 of these procedures.

Section 44. Tentative Report of the Expert Panel.

(a) After following the procedures established in Section 30(j), and prior to issuing a Final Report as described in Section 45 of these procedures, the Expert Panel shall issue a Tentative Report.

(b) The Tentative Report of the Expert Panel shall meet all of the requirements established for a Final Report in Sections 45(a) and (b) of these procedures.

(c) The public notice of the availability of the Tentative Report shall provide 60 days within which any interested person may submit comments on the Tentative Report and a request for oral hearing before the Expert Panel on the Tentative Report.

(d) An oral hearing shall be granted by the Expert Panel on a Tentative Report of the Expert Panel for good cause shown. Any such oral hearing shall be conducted pursuant to the provisions of Section 39 of these procedures.

Section 45. Final Report of the Expert Panel.

(a) With respect to each cosmetic ingredient (or, where appropriate, closely related group of cosmetic ingredients), the Expert Panel shall issue a Final Report. The Final Report shall state the determination of the Expert Panel in accordance with Section 42 of these procedures with respect to each ingredient and any relevant conditions of its use.

(b) The Final Report shall contain the complete discussion, conclusions, and recommendations of the Expert Panel with respect to the ingredient involved, including a full explanation of the reasons for those conclusions and recommendations and references to the scientific information on which the Expert Panel relies.

(c) The minutes or other record of the meeting in which a Final Report is issued shall respond to each point made in any submission or oral statement make with respect to the Tentative Report pursuant to Section 44 of these procedures.

(d) The Executive Director shall arrange for the publication of each Final Report in an appropriate, peer reviewed scientific journal, and arrange for public dissemination of the Final Report.

(e) The Executive Director shall send to the Commissioner of Food and Drugs, with a copy to the Director of the Center for Food Safety and Applied Nutrition and the Director of the Office of Cosmetics and Colors, a copy of each Final Report, calling attention to any determination by the Expert Panel that:

(1) an ingredient is unsafe under its intended conditions of use.

(2) there are insufficient data or information needed to make a determination that the ingredient is safe under its intended conditions of use (see Section 46).

(3) limitations on the conditions of use of the ingredient are needed in order to assure safety.

Section 46. Classification of Ingredients Determined to Have Insufficient Data or Information.

(a) The Executive Director shall establish three categories of ingredients for which the Expert Panel has made a determination under Section 42 and Section 45(e)(2) that there are

insufficient data or information to make a determination that the ingredient is safe under its intended conditions of use.

(1) Any such ingredient for which there is no reported use in the VCRP ingredient database under 21 C.F.R. Part 720 shall be classified as "No Reported Use."

(2) Any such ingredient for which there is a reported use in the VCRP ingredient database shall be classified as "Insufficient Data or Information" for two years after the Expert Panel Final Report is issued.

(3) Any such ingredient for which there is a reported use in the VCRP ingredient database for more than two years after the Expert Panel Final Report shall be classified as "Use Not Supported by the Data and Information Submitted to the Expert Panel."

(b) The Executive Director shall at least annually verify the classification of each such ingredient.

(c) The Expert Panel may at any time determine in accordance with the procedures in Section 47 to amend its Final Report with respect to any such ingredient.

(d) For any such ingredient for which the Final Report was issued prior to the date that this Section of the Procedures was approved, the two year period for the "Insufficient Data or Information" classification under Subsection (a)(2) shall begin on the date of the approval of this Section.

Section 47. Amendment and Re-Review of a Final Report.

(a) Any interested person who believes that a Final Report is incorrect may petition the Expert Panel to amend the Final Report to correct such error. The Executive Director shall give public notice of any such petition and all proceedings of the Expert Panel with respect to any such petition shall be conducted pursuant to these procedures.

(b) A petition to amend a Final Report pursuant to this section shall ordinarily be based upon new data and information not previously reviewed by the Expert Panel. Such a petition shall be used primarily after the further data and information requested by the Expert Panel in the Final Report with respect to an ingredient for which the Expert Panel has made a determination that there is a lack of information needed to make a determination that the ingredient is safe under its intended conditions of use, under each relevant condition of use, has been obtained, so that the Expert Panel can proceed with a final determination with respect to that ingredient or condition.

(c) A determination by the Expert Panel with respect to a petition for amendment of the Final Report shall be handled in the same way as the initial determination by the Expert Panel. After following the procedures established in Section 30(j), the Expert Panel shall first issue a Tentative Amended Report in accordance with Section 44 and then a Final Amended Report in accordance with Section 45.

(d) The Expert Panel may, in its discretion or at the request of the Chair of the Steering committee, consider a re-review of any Final Report.

(1) Consideration of such a re-review may be based upon new data and information or the passage of substantial time since publication of the Final Report.

(2) If the Expert Panel concludes that a re-review is warranted, such re-review shall follow the process established in these procedures for the initial review of the ingredient.

(3) If the Expert Panel concludes, after considering any new data and information that have become available since publication of the Final Report, that a re-review is not warranted, the Expert Panel may issue a statement of its reasons for that conclusion in a Re-Review Summary for publication.

(4) The Executive Director shall give advance public notice that the Expert Panel is considering the re-review of an ingredient and invite public comment and participation.

(e) The Expert Panel may consider adding ingredients to any Final Report during the re-review process in (d) above.

(1) The Executive Director shall give advance public notice of the intent to add ingredients, in addition to those in the original Final Report, including the opportunity for any interested party to comment and/or provide additional published or unpublished data relating to those additional ingredients.

(2) If the Expert Panel concludes that the data in the original Final Report substantially addresses the safety of the expanded list of ingredients, a Tentative Amended Final Report shall be issued that includes the data in the original Final Report plus all available new published and unpublished data for the expanded list of ingredients.

(3) Opportunity for public comment on such a Tentative Amended Final Report shall be provided as in Section 44.

Part E -- Public Notice and Availability of Records

Section 50. Public Notice.

(a) The Executive Director shall give public notice of the availability of all Scientific Literature Reviews, the meetings of the Expert Panel, decisions and reports of the Expert Panel, and all other similar information, in each of the following ways:

(1) Such notice shall be sent to a permanent list consisting of representative members of the press (including interested newspapers, trade press, consumer publications, professional publications, and others) and representative interested organization (including consumer, professional, and business organizations).

(2) Such notice shall also be sent to specific individuals who have demonstrated a continuing interest through direct participation in the CIR except for individuals who are members of organizations to which notice is provided.

(3) Such notice shall be provided on the CIR website.

(b) Any interested individual or organization may request that it be placed on the list for all public notices by written application to the Executive Director. Any such request shall be accompanied by a statement of the need of such individuals for such notices.

Section 51. Availability of Records for Public Disclosure.

(a) The following records relating to the CIR shall be available for public disclosure at the following time, except as otherwise provided in paragraph (b) of this section:

(1) The minutes of each Steering Committee meeting, after they have been approved by the Steering Committee Chair.

(2) Each Scientific Literature Review, at the time it is completed and available in printed form.

(3) Each submission of safety information pursuant to Section 30(e) of these procedures, at the time it is received by the Executive Director.

(4) The written information made available for consideration by the Expert Panel at any meeting, at the same time that it is made available.

(5) Any transcript of an Expert Panel meeting, as soon as it is available.

(6) The minutes of any portion of an Expert Panel meeting, after they have been approved by the Expert Panel and certified by the Expert Panel Chair.

(7) All written data, information, or views submitted to the Expert Panel at any portion of a meeting, as soon as they are so submitted.

(8) Reserved

(9) Any formal advice, statement, or report of the Expert Panel, after it has been issued by the Expert Panel.

(10) Any other Expert Panel records relating to the matter involved, after the matter relevant to those records is acted upon by the Expert Panel, or upon a determination by the Expert Panel that such records may be made available for public disclosure without undue interference with the operations of the Expert Panel.

(b) The following records relating to the CIR shall not be available for public disclosure:

(1) Records relating to any cosmetic ingredient which has been determined by the Food and Drug Administration to be exempt from public disclosure pursuant to 21 C.F.R. 701.3(a) and 720.8(a).

(2) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall be available for public disclosure only in accordance with the regulations established by the Food and Drug Administration for public disclosure of such data and information in 21 C.F.R. Part 20.

(3) All data and information relative to the nomination and selection of the members of the Expert Panel and liaison representative, in accordance with Section 21(e) of these procedures.

(4) Reserved

(5) Documents of working teams of Expert Panel members which have not been submitted to the Expert Panel.

Section 52. Reserved

Section 53. Public Inquiries and Requests for the CIR Records.

(a) Public inquiries on all matters relating to the CIR shall be directed to the CIR Executive Director.

(b) All requests for records relating to the CIR, including records of the Expert Panel, shall be made to the Executive Director.

(c) Copies of records that are publicly available pursuant to these procedures shall be made upon request for a fee that is designed only to recoup the actual cost of providing the copies. The Executive Director may, in the Executive Director's sole discretion, waive any such fee.